

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KONINKLIJKE PHILIPS N.V. and IP2IPO)	
INNOVATIONS, LTD.,)	
)	
Plaintiff,)	
)	C.A. No.
v.)	
)	JURY TRIAL DEMANDED
OPSSENS INC., OPSSENS MEDICAL,)	
OPSSENS MEDICAL INC., and)	
HAEMONETICS CORPORATION,)	
)	
Defendant.)	

**COMPLAINT FOR PATENT INFRINGEMENT
AND DEMAND FOR JURY TRIAL**

Koninklijke Philips N.V. (“Philips”) and IP2IPO Innovations, Ltd. (“IP2IPO”) (collectively, “Plaintiffs”), by way of this Complaint against Defendants OpSens Inc., OpSens Medical, OpSens Medical Inc., (collectively, “OpSens”) and Haemonetics Corporation (all collectively, “Defendants”), allege upon information and belief as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 10,912,463 (the “’463 Patent”) arising under the United States patent laws, Title 35, United States Code, § 1 et. seq., including 35 U.S.C. §§ 271 and 281.

2. The ’463 Patent is related to interventional cardiology or percutaneous coronary intervention (“PCI”). A true and accurate copy of the ’463 Patent is attached hereto as Exhibit A.

THE PARTIES

3. Plaintiff Koninklijke Philips N.V. (“Philips N.V.”) is a corporation duly organized and existing under the laws of the Netherlands. Its principal place of business is High Tech Campus 5, 5656 AE Eindhoven, the Netherlands.

4. Plaintiff IP2IPO is a wholly-owned subsidiary of IP Group, PLC, which is a public limited company duly organized and existing under the laws of the United Kingdom, with a place of business at 2nd Floor, 3 Pancras Square, King's Cross, London N1C 4AG.

5. IP2IPO and Philips are the assignees and co-owners of the '463 Patent.

6. Defendant OpSens Inc. is a corporation duly organized and existing under the laws of the province of Québec, Canada with its principal place of business at 750 Bd. Du Parc Technologique, Québec, QC, G1P 4S3, Canada. Defendant OpSens Inc. is a wholly-owned subsidiary of Haemonetics Corporation.

7. Defendant OpSens Inc. is in the business of, *inter alia*, manufacturing, marketing, and/or selling interventional cardiology or PCI devices throughout the United States, including the State of Delaware.

8. Defendant OpSens Medical is a corporation duly organized and existing under the laws of the province of Québec, Canada with its principal place of business at 750 Bd. Du Parc Technologique, Québec, QC, G1P 4S3, Canada.

9. Defendant OpSens Medical is in the business of, *inter alia*, manufacturing, marketing, and/or selling interventional cardiology or PCI devices throughout the United States, including the State of Delaware.

10. Defendant OpSens Medical Inc. is a corporation duly organized and existing under the laws of the state of Delaware, with its registered agent, Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE, 19808, USA.

11. Defendant OpSens Medical Inc. is in the business of, *inter alia*, manufacturing, marketing, and/or selling interventional cardiology or PCI devices throughout the United States, including the State of Delaware.

12. Defendant Haemonetics Corporation is a corporation duly organized and existing under the laws of the state of Delaware, with its registered agent, Corporation Trust Company, located at 1209 Orange Street, Wilmington, DE, 19801, USA.

13. Defendant Haemonetics Corporation is in the business of, *inter alia*, manufacturing, marketing, and/or selling interventional cardiology or PCI devices throughout the United States, including the State of Delaware.

THE ASSERTED PATENT

U.S. Patent 10,912,463

14. The '463 Patent is entitled "Devices, Systems, and Methods for Assessing a Vessel." The '463 Patent issued on February 9, 2021 to inventors Justin Davies, Joseph Burnett, Neil Hattangadi, David Anderson, and Helen Davies. IP2IPO and Philips are the assignees and co-owners of the '463 Patent. *See* Exhibit A.

15. The marking requirements of 35 U.S.C. § 287 for the '463 Patent have been complied with by, *inter alia*, virtually marking Philips products on its website: <https://www.philips.com/a-w/about/innovation/ips/contact-and-support/patent-marking.html>.

JURISDICTION AND VENUE

16. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

17. This is an action for patent infringement arising under the patent laws of the United States. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

18. This Court has personal jurisdiction over OpSens Inc. because OpSens Inc. conducts business in and has committed acts of patent infringement, contributed to infringement by others, and/or induced others to commit acts of patent infringement in this District, the State of Delaware, and elsewhere in the United States and has established minimum contacts with this forum state such that the exercise of jurisdiction over OpSens Inc. would not offend the traditional notions of fair play and substantial justice. OpSens Inc. transacts substantial business with entities and individuals in the State of Delaware and this District, by among other things, importing, offering to sell, distributing, and selling products that infringe the '463 Patent,

including the infringing Accused Products and components thereof that OpSens Inc. purposefully directs into the State of Delaware and this District as alleged herein, as well as by providing service and support to its customers in this District. OpSens Inc. places the accused PCI products and components thereof into the stream of commerce via authorized and established distribution channels with the knowledge and expectation that they will be sold in the State of Delaware, including this District.

19. This Court has personal jurisdiction over OpSens Medical because OpSens Medical conducts business in and has committed acts of patent infringement, contributed to infringement by others, and/or induced others to commit acts of patent infringement in this District, the State of Delaware, and elsewhere in the United States and has established minimum contacts with this forum state such that the exercise of jurisdiction over OpSens Medical would not offend the traditional notions of fair play and substantial justice. OpSens Medical transacts substantial business with entities and individuals in the State of Delaware and this District, by among other things, importing, offering to sell, distributing, and selling products that infringe the '463 Patent, including the infringing Accused Products and components thereof that OpSens Medical purposefully directs into the State of Delaware and this District as alleged herein, as well as by providing service and support to its customers in this District. OpSens Medical places the accused PCI products and components thereof into the stream of commerce via authorized and established distribution channels with the knowledge and expectation that they will be sold in the State of Delaware, including this District.

20. This Court has personal jurisdiction over OpSens Medical Inc. because OpSens Medical Inc. is incorporated in Delaware. OpSens Medical Inc. also conducts business in and has committed acts of patent infringement, contributed to infringement by others, and/or induced others to commit acts of patent infringement in this District, the State of Delaware, and elsewhere in the United States and has established minimum contacts with this forum state such that the exercise of jurisdiction over OpSens would not offend the traditional notions of fair play and substantial justice. OpSens transacts substantial business with entities and individuals in the

State of Delaware and this District, by among other things, importing, offering to sell, distributing, and selling products that infringe the '463 Patent, including the infringing Accused Products and components thereof that OpSens purposefully directs into the State of Delaware and this District as alleged herein, as well as by providing service and support to its customers in this District. OpSens places the accused PCI products and components thereof into the stream of commerce via authorized and established distribution channels with the knowledge and expectation that they will be sold in the State of Delaware, including this District.

21. This Court has personal jurisdiction over Haemonetics Corporation because Haemonetics Corporation, including by and through OpSens, conducts business in and has committed acts of patent infringement, contributed to infringement by others, and/or induced others to commit acts of patent infringement in this District, the State of Delaware, and elsewhere in the United States and has established minimum contacts with this forum state such that the exercise of jurisdiction over Haemonetics Corporation would not offend the traditional notions of fair play and substantial justice. OpSens' website notes, for example, that "OpSens is now part of HAEMONETICS®." See *OpSens Receives dPR Clearance from FDA*, OpSens.com (last accessed January 1, 2024) <https://opsens.com/2019/2789/>. Haemonetics Corporation transacts substantial business with entities and individuals in the State of Delaware and this District, by among other things, importing, offering to sell, distributing, and selling products that infringe the '463 Patent, including the infringing Accused Products and components thereof that Haemonetics Corporation purposefully directs into the State of Delaware and this District as alleged herein, as well as by providing service and support to its customers in this District. Haemonetics Corporation places the accused PCI products and components thereof into the stream of commerce via authorized and established distribution channels with the knowledge and expectation that they will be sold in the State of Delaware, including this District.

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(c) and 1400(b), because Defendants have committed acts of infringement in this District, including at least the sale of infringing Accused Products in this District, because Defendants maintain

regular and established places of business in this District, and because at least one of the Defendants was incorporated in the State of Delaware.

FACTS

23. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

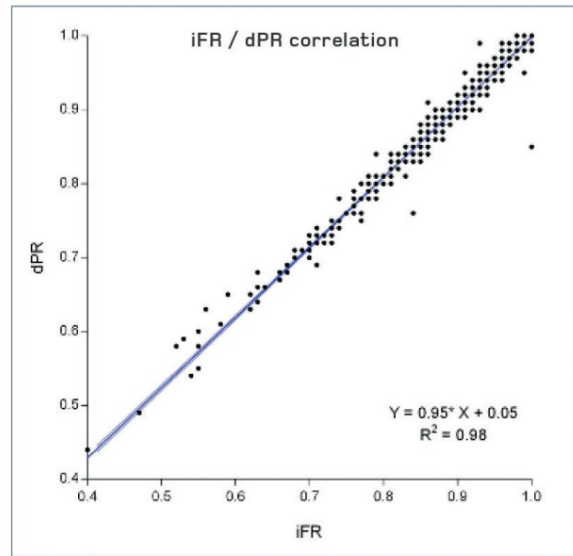
24. Philips is a leading designer and supplier of medical devices for use in PCI procedures. Philips' integrated cardiology ecosystem of data and devices work together to help doctors and medical professionals provide efficient and effective cardiac care in the most appropriate setting. Working in partnership with health systems and healthcare professionals in their financial and operational goals, Philips drives innovation.

25. IP2IPO and its parent company, IP Group, focus their business on identifying, co-founding or creating companies based on fundamental science and innovation, which is often generated within one of the World's leading universities or research institutions. IP Group provides capital and expertise in return for a shareholding in such companies and seeks to grow the value of such shareholdings over time before selling down in whole or over a period to generate funds either for re-investment or to make returns to its shareholders. In addition, IP Group has a limited intellectual property licensing business.

26. For years, patients who needed to be diagnosed for heart problems have been assessed using a procedure called "Fractional Flow Reserve" or "FFR." To take an FFR measurement, a cardiologist inserts a blood pressure sensor into a patient's coronary artery, then measures differences in blood pressure at various points along the coronary artery. By detecting drops in blood pressure, FFR allows the cardiologist to locate a narrowing (or "stenosis") in the blood vessel.

27. But FFR requires the use of uncomfortable vasodilating drugs such as adenosine. These drugs induce hyperemia—a stress test of the heart that dilates the patient's blood vessels. Chest pains, nausea, redness of the face, and stomach pain are all possible side effects of vasodilating drugs. For some patients, these drugs may also increase the risk of heart attack.

28. Philips offers patients an innovative procedure that accurately measures changes in blood pressure without any need for vasodilating drugs. Philips calls this procedure “Instantaneous Wave-Free Ratio,” or “iFR.” The background technology upon which iFR was developed was patented, including in the ’463 Patent.



29. iFR is the leading hyperemia-free physiologic index for measuring pressure in diagnostic and interventional procedures, a leading pressure ratio recognized across the industry by both Philips’ customers and competitors. *See* Gotberg M, et al. *Instantaneous wave-free ratio compared with fractional flow reserve in PCI: A cost-minimization analysis*, INT. J. CARDIO. 2021 1;344:54-59. Unlike FFR, iFR is a non-hyperemic pressure index. iFR avoids the use of hyperemia-inducing drugs by carefully measuring blood pressure only during certain portions of the cardiac cycle where the fluid dynamics in the blood vessel are fairly stable.

30. Defendants, too, recognize iFR as a leading industry product. After Philips began offering iFR to patients, OpSens began marketing “dPR”—another non-hyperemic index that measures blood pressure only during certain portions of the cardiac cycle. OpSens markets its new “dPR” ratio by telling customers that it is just like Philips’ iFR. *See* Exhibit B at 2 (plotting patient iFR against dPR to show correlation, stating that “RESTING INDICES ARE EQUIVALENT.”).

31. OpSens told the Food and Drug Administration (“FDA”) that its new dPR product was “equivalent to iFR” to get quick approval. Exhibit C at 4. (“dPR is a resting index for the diagnostic [sic] of the severity of stenosis *equivalent to iFR (instantaneous wave-Free Ratio)*”) (emphasis added).

32. iFR is a leading industry pressure ratio, but it is also covered by the Plaintiffs' intellectual property. As one example, the '463 patent includes embodiments covering hyperemia-free pressure ratios. *See generally* Exhibit A. By copying iFR for use in its own products, OpSens has infringed the claims of the '463 patent asserted herein.

THE ACCUSED PRODUCTS

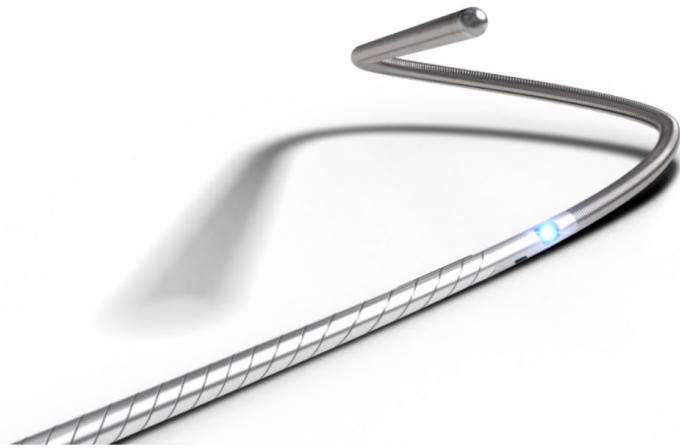
33. Plaintiffs incorporate by reference every allegation set forth in the foregoing paragraphs of this Complaint as if fully set forth and restated herein.

34. The Accused Products include OpSens' interventional cardiology or PCI host systems (e.g., OpSens' OptoMonitor, Optical Box, Handle Unit, LifeSens, MultiSens, AccuSens and OEM-MNP systems), intravascular measurement devices (e.g., SavvyWire, OpSens' OptoWire, OptoWire DEUX, and OptoWire III systems), pressure sensors (e.g., OpSens' OPP-M200 series and Fidela systems), catheters (e.g., OpSens' XTender system) and/or systems performing a Diastolic Pressure Ratio ("dPR").

35. OpSens' website advertises its "OptoWire" product line for use in "measur[ing] physiologic indices including Fractional Flow Reserve (FFR and diastolic Pressure Ratio (dPR))." *Optowire*, OPSSENSMEDICAL,

<https://opsensmedical.com/products/op>

[towire/](https://opsensmedical.com/products/optowire/) (last visited Feb. 14, 2024). OpSens' website shows an image of its OptoWire (included on the right). Per OpSens, the "OptoWire is a modern pressure guidewire designed to assess stenoses in vessels such as coronary arteries." *Id.*



36. OpSens' website for OptoWire also shows certain "Related Products" at the bottom of the page. These include the "OptoMonitor" system and "OEM Solutions" pages.

OptoMonitor, OPSenseMEDICAL, <https://opsensmedical.com/products/optomonitor/> (last visited Feb. 14, 2024)

Related Products



37. The remaining Accused Products comprise additional auxiliary products that, may be used in infringing combinations with the OptoWire and OptoMonitor product lines. These include, for example, intermediary stems that may connect the OptoWire to a receiving device such as the OptoMonitor (e.g., the “Handle Unit” and “Optical Box”) or catheters that may be used to house the OptoWire (e.g., the “OpSens’ XTender system”). As one example, the OpSens website describes the “Handle Unit” as able to “[c]onnect OptoWire with Optical Box” and the “Optical Box” as able to “send/receive light to/from OptoWire.” *Id.*



38. Defendants have infringed and continue to infringe at least the exemplary claims identified below of the '463 Patent. Defendants infringe the exemplary claim of the '463 Patent literally and/or under the doctrine of equivalents by making, using, and selling products that infringe, by importing those products into the United States to offer them for sale, and/or by selling those products within the United States after importation.

CLAIM FOR RELIEF

Patent Infringement of the '463 Patent under 35 U.S.C. § 271

39. Plaintiffs incorporate by reference every allegation set forth in the foregoing paragraphs of this Complaint as if fully set forth and restated herein.

40. Defendants, without the authority or consent of Philips or IP2IPO, have been making, using, importing, offering to sell and selling, and continues to make, use, import, offer and sell in the United States Accused Products that infringe at least claims 1, 11, and 26 of the '463 Patent.

41. A claim chart laying out an exemplary infringement analysis of claims 1, 11 and 26 of the '463 Patent based on publicly available information is heretofore attached as Exhibit D.

42. Defendants infringe at least claims 1, 11, and 26 of the '463 Patent directly and indirectly by causing direct infringement in the United States. Defendants will have had knowledge of the '463 Patent and the infringing nature of its Accused Products at least as of the date of service of this Complaint. Defendants through contributory infringement by selling or offering for sale to third parties, such as its customers, products that are material parts of the inventions claimed in the '463 Patent, knowing that they were especially made or especially adapted to practice one or more of the claims of the '463 Patent, and that have no substantial noninfringing uses, and knowing they are in fact used to directly infringe one or more of those claims, at least through the allegations in this Complaint. Defendants also infringe at least one claim of the '463 Patent indirectly through inducement by, inter alia, importing, offering to sell and/or selling the Accused Products to third parties, including its customers, with the specific intent that those third parties directly infringe one or more of the claims of the '463 Patent. Defendants actively encourage or aid such infringement through various activities, including descriptions on its website and related materials, and knows—at least through the allegations in this Complaint—that the third parties' acts it has induced, and continues to induce, constitute infringement.

43. Defendants' infringement of the '463 Patent has caused and continues to cause damages and irreparable harm to Philips and IP2IPO.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court enter judgment in their favor on each and every claim for relief set forth above and award them including, but not limited to, the following:

A. The entry of judgement under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' Accused

Products prior to the expiration of the '463 Patent will infringe, actively induce infringement, and/or contribute to the infringement of the '463 Patent under 35 U.S.C. § 271(a), (b) and/or (c);

B. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, or selling Defendants' Accused Products within the United States, or importing Defendants' Accused Products into the United States, until the expiration of the '463 Patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

C. The issuance of an order that Defendants certify that they have destroyed all infringing products in its possession;

D. An award to Plaintiffs adequate to compensate for Defendants' infringement pursuant to 35 U.S.C. § 284, in an amount to be determined at trial, as a result of Defendants' infringement of the '463 Patent;

E. Granting Plaintiffs pre- and post-judgment interest on damages, together with all costs and expenses;

F. Granting Plaintiffs reasonable attorney fees pursuant to 35 U.S.C. § 285; and

G. Awarding such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs respectfully request a trial by jury on all claims so triable.

Respectfully submitted,

/s/ Karen E. Keller

Karen E. Keller (No. 4489)

Andrew E. Russell (No. 5382)

SHAW KELLER LLP

I.M. Pei Building

1105 North Market Street, 12th Floor

Wilmington, DE 19801

(302) 298-0700

kkeller@shawkeller.com

arussell@shawkeller.com

*Attorneys for Koninklijke Philips N.V.,
IP2IPO Innovations, Ltd.*

OF COUNSEL:

Frank A. DeCosta III, Ph.D.

Alexander E. Harding

FINNEGAN, HENDERSON, FARABOW,

GARRETT & DUNNER, L.L.P.

901 New York Avenue, N.W.

Washington, D.C. 20001-4413

(202) 408-4000

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